DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 30 2003

Aerocrine AB
c/o Mr. Sean M. Curry
COO, Certified Software Solutions, Inc.
16787 Bernardo Center Drive – Suite A-1
San Diego, CA 92128

Regulation Number: 21 CFR §862.3080
Classification: II
Product Code: MXA

Re: K021133 – Automatic Evaluation of Class III Designation
NIOX® Breath Nitric Oxide Test System

Dear Mr. Curry:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the Breath Nitric Oxide Test System that is intended to measure nitric oxide in human breath. Measurement of changes in fractional nitric oxide concentration in expired breath aids in evaluating an asthma patient's response to anti-inflammatory therapy, as an adjunct to established clinical and laboratory assessments of asthma. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Breath Nitric Oxide Test System, and substantially equivalent devices of this generic type into class II under the generic name breath nitric oxide test system. This order also identifies the special controls applicable to this type of device.

FDA identifies this generic type of device as:

21 CFR 862.3080 Breath Nitric Oxide Test System

A breath nitric oxide test system is a device intended to measure fractional nitric oxide in human breath. Measurement of changes in the fractional nitric oxide concentration in expired breath aids in evaluating an asthma patient's response to anti-inflammatory therapy, as an adjunct to established clinical and laboratory assessments of asthma. A breath nitric oxide test system combines chemiluminescence detection of nitric oxide with a pneumotachograph, display and dedicated software.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified

into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, with in 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device.

On March 17, 2003, FDA filed your petition requesting classification of the nitric oxide breath test system into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on March 14, 2003 automatically classifying the nitric oxide breath test system in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, which was subsequently reclassified into class I or class II. In order to classify the breath nitric oxide test system into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the petition, FDA has determined that the NIOX® Breath Nitric Oxide Test System that is intended to aid in evaluating an asthma patient's response to anti-inflammatory therapy by measuring changes in fractional exhaled nitric oxide concentration in asthma patients, as an adjunct to established clinical and laboratory assessments of asthma can be classified in class II with the establishment of a special control. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device type. Therefore, in addition to the general controls of the act, the NIOX® Breath Nitric Oxide Test System is subject to the following special controls: Class II Special Controls Guidance Document: Breath Nitric Oxide Test System: Guidance for Industry and FDA.

The Class II Special Controls Guidance Document identifies the potential risk presented by the device as improper patient management.

FDA believes the following controls identified in the Class II Special Controls Guidance Document, when combined with the general controls of the act, will provide reasonable assurance of the safety and effectiveness of this type of device:

1. Recommendations for labeling; and

2. Performance studies.

Following the effective date of a final rule reclassifying the device, any firm submitting a 510(k) premarket notification for a breath nitric oxide test system will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the device is not exempt from the premarket notification requirements. Thus, persons who intend to market this device must submit to FDA a premarket notification submission containing information on the breath nitric oxide test system they intend to market prior to marketing the device.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market this device, subject to the general control provisions of the act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Jean M. Cooper, M.S., D.V.M., Division of Chemistry and Toxicology Device at (301) 594-1243.

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health